

REMARKS and ARGUMENTS

The Claims have been amended by amending Claim 1.

Claims 1, 4, 7-18, 20, 21, and 51-55 are pending in this application. Of the pending Claims, Claims 1, 7, 8, 20, 21, and 51-53, and 55 were rejected in the August 7, 2006 Office Action. Claims 4, 9-18, and 54 were objected to for reasons of form as being dependent on a rejected base Claim, but were otherwise found to be allowable in substance.

Claim 1 has been amended to delete the reference to the former first alternative peptidyl sequence. Claim 1 has also been amended in its part (c) to say that "(S)_n is a hydrophilic region ~~comprising~~ consisting of hydrophilic amino acids or other hydrophilic groups"

This amendment is made without prejudice to Applicants' right to pursue the canceled subject matter in one or more continuation applications.

The § 119(e) Priority Date

The Office has acknowledged that Claims 53 and 54 are entitled to the benefit of the provisional priority date, but has taken the position that the other pending Claims are not.

Applicants do not concede that the remaining Claims are not also entitled to the benefit of the provisional filing date. Applicants reserve the right to demonstrate such priority at a later date, should the need arise. However, it is respectfully submitted that it is not necessary to decide this question for the time being. With the exception of Claims 53 and 54, in the discussion below it will be assumed for the sake of argument that the Claims might only be entitled to the benefit of the later nonprovisional filing date. Even if one makes this assumption, for the reasons given below it is respectfully submitted that all grounds of rejection should be withdrawn.

Preliminary Note Concerning the Novelty of the Independent Claims

Claims 1 and 53 are the two independent Claims. If the independent Claims are novel and nonobvious, it then logically follows that the dependent Claims are necessarily novel and nonobvious as well. See M.P.E.P. § 2143.03, first paragraph. Therefore, the following discussion of novelty focuses on the two independent Claims, Claims 1 and 53, which are addressed separately.

The §§ 102 (a) and (b) Rejections of Independent Claim 1

Applicants do not waive any of their earlier arguments concerning novelty, and reserve the right to present those arguments anew at a later date.

The *Organic Letters* Paper.

It is respectfully submitted that the present amendment to Claim 1 clearly distinguishes Claim 1 from the *Organic Letters* paper.

In particular, part (c) of amended Claim 1 now includes the limitation that

(S)_n is a hydrophilic region ~~comprising~~ consisting of hydrophilic amino acids or other hydrophilic groups; wherein *n* is from 4 to 10, and wherein said hydrophilic region has a size not larger than about the size of a decapeptide.

The fifth peptidyl sequence. The August 7, 2006 Office Action at page 3, paragraph 4 asserted that a compound disclosed in the Fu *et al. Organic Letters* paper would have anticipated the fifth peptidyl sequence of Claim 1 (as Claim 1 was then written), with (S)_n being Dpg-Lys₆-NH₂.

Claim 1 as amended requires that (S)_n must be “a hydrophilic region consisting of hydrophilic amino acids or other hydrophilic groups.” The Dpg-Lys₆ moiety does not satisfy the amended limitation defining (S)_n.

“Dpg” is an abbreviation for C^{α,α}-dipropylglycine, which is a hydrophobic amino acid. See footnote 3 on page 237 of the *Organic Letters* paper. The moiety Dpg-Lys₆ thus contains a hydrophobic amino acid, namely Dpg. Thus the moiety does not satisfy the limitation of amended Claim 1 that (S)_n must be a region “consisting of hydrophilic amino

acids or other hydrophilic groups.” The *Organic Letters* paper does not anticipate the fifth peptidyl sequence of Claim 1 as amended.

The first peptidyl sequence. The August 7, 2006 Office Action at page 3, paragraph 4 also asserted that the same compound from the Fu *et al.* *Organic Letters* paper would have anticipated the first peptidyl sequence of Claim 1 (as Claim 1 was then written). The former first peptidyl sequence of Claim 1 has been deleted by the present amendment, thus making that ground of rejection moot.

Organic Letters Paper Summary. It is respectfully submitted that the present amendments overcome the rejection of independent Claim 1 over the *Organic Letters* paper.

The Aucoin Oral Presentation.

Applicants have previously submitted the December 19, 2005 Affidavit of Inventor Robert Hammer to show that the Aucoin oral presentation represented, at least in pertinent part, the inventors’ own work, and that the presentation was therefore removed as a reference under § 102(a).

The Office has repeated the rejection of independent Claim 1 as being anticipated by the Aucoin presentation under § 102(a). The Office has again dismissed the Hammer Affidavit as a basis for removing the Aucoin presentation.

With all respect, the undersigned genuinely does not understand the Office’s rationale in dismissing the Hammer Affidavit.

The June 27, 2006 Request for Continued Examination, at page 5, expressly requested the Office “to clarify this ground of rejection, to explain with greater specificity what the Office believes is lacking from the Hammer Affidavit, so that a more responsive reply might be made.” With all respect, the Office’s latest remarks are still not understood. For the reasons given in the Request for Continued Examination (pages 4-5), reasons that will not be spelled out again in the interest of brevity; and also for the additional reasons given below; it is respectfully submitted that the rejection based on the Aucoin presentation should be withdrawn.

Strictly in the alternative, should the Office repeat this ground of rejection, the Office is respectfully requested to specify – in detail – more precisely why the Office has found the December 2005 Hammer Affidavit insufficient to remove the Aucoin presentation as a reference. If the Office believes, for example, that the rejection might be overcome by some modification to the Affidavit's language, then the Office is respectfully requested to suggest a proposed modification for Applicants' consideration.

The August 7, 2006 Office Action's entire remarks concerning the Aucoin presentation and the Hammer Affidavit were the following (pages 7-8):

Applicants contend that the Hammer affidavit shows that the sequence and synthesis of peptides AMY-1 and AMY-3 was conceived by Drs. Hammer, McLaughlin, Fu, and Miller. However, all six of the instant inventors are presumed to be the inventors of the subject matter of the rejected claims, absent evidence to the contrary. Accordingly, the peptides AMY-1 and AMY-3, disclosed by the Aucoin oral presentation and which the affidavit states was invented by Inventors Hammer, McLaughlin, Fu, and Miller is still "by another" and remains available as prior art under 35 U.S.C. 102(a).

With all respect, it is difficult to understand just what the Office intended to assert in the passage quoted above, particularly when the Office Action also acknowledged, on page 6:

This rejection could be overcome, e.g., by the submission of a declaration under 37 CFR 1.132 showing that the subject matter of the presentation was derived from the instant inventors and was therefore not 'by another.' See MPEP 715.01(c), 716.10, and 2136.05."

The patent statute expressly provides that inventors "may apply for a patent jointly even though . . . (3) each did not make a contribution to the subject matter of every claim of the patent." 35 U.S.C. § 116. The patent statute makes clear that, as a substantive matter, no presumption exists that all named inventors are necessarily co-inventors of all claims. To the extent that any such assumption is made during prosecution, it is strictly a procedural convenience, an assumption that is provisionally made until some question arises in prosecution for which it may become genuinely important to distinguish who is actually an inventor on which Claims.

While the Office may be correct in saying that “all six of the instant inventors are presumed to be the inventors of the subject matter of the rejected claims, absent evidence to the contrary,” this is an provisional assumption only, and it is not a particularly strong presumption in light of 35 U.S.C. § 116.

See generally M.P.E.P. § 716.10, relevant portions of which are reproduced below (with citations omitted):

716.10 Attribution

Under certain circumstances an affidavit or declaration may be submitted which attempts to attribute an activity, a reference or part of a reference to the applicant. If successful, the activity or the reference is no longer applicable. . . .

Where there is a published article identifying the authorship (MPEP § 715.01(c)) . . . that discloses subject matter being claimed in an application undergoing examination, the designation of authorship . . . does not raise a presumption of inventorship with respect to the subject matter disclosed in the article

However, it is incumbent upon the inventors named in the application . . . to rebut a rejection under 35 U.S.C. 102(a) . . . to provide a satisfactory showing by way of affidavit under 37 CFR 1.132 that the inventorship of the application is correct in that the reference discloses subject matter derived from the applicant rather than invented by the author . . . Inquiry is appropriate to clarify any ambiguity created by an article regarding inventorship and it is then incumbent upon the applicant to provide "a satisfactory showing that would lead to a reasonable conclusion that [applicant] is the ... inventor" of the subject matter disclosed in the article and claimed in the application.

An uncontradicted "unequivocal statement" from the applicant regarding the subject matter disclosed in an article . . . will be accepted as establishing inventorship. However, a statement by the applicants regarding their inventorship in view of an article, patent, or published application may not be sufficient where there is evidence to the contrary. . . .

EXAMPLES

The following examples demonstrate the application of an attribution affidavit or declaration.

Example 1

During the search the examiner finds a reference fully describing the claimed invention. The applicant is the author . . . and it was published . . . less than one year prior to the filing date of the application. The reference cannot be used against applicant since it does not satisfy the 1-year time requirement of 35 U.S.C. 102(b).

Example 2

Same facts as above, but the author . . . is an entity different from applicant. Since the entities are different, the reference is prior art under 35 U.S.C. 102(a)

In the situation described in Example 2, an affidavit under 37 CFR 1.132 may be submitted to show that the relevant portions of the reference originated with or were obtained from applicant. Thus the affidavit attempts to convert the fact situation from that described in Example 2 to the situation described in Example 1.

Note particularly the admonition in § 716.10 that an uncontradicted, unequivocal statement from the applicant regarding the subject matter disclosed in an article should be accepted as establishing inventorship, unless there is evidence to the contrary.

The Hammer Affidavit provides a clear, uncontradicted, unequivocal statement regarding the subject matter disclosed in the pertinent portion of the Aucoin presentation. See particularly sections 2 and 7 of the Affidavit. Unless the Office produces some countervailing evidence, these statements must be accepted as true. Accepting those statements as true has the direct, logical consequence of removing the Aucoin presentation as a reference.

The Office is respectfully requested to withdrawn this ground of rejection. Strictly in the alternative, the Office is respectfully requested to clarify with greater specificity why the Hammer Affidavit was found not to overcome the rejection, so that a more responsive reply might be made. Further in the alternative, the Office is respectfully requested to suggest any specific modifications to the language of the Affidavit that might help overcome any deficiencies that the Office may identify in the Affidavit.

The Fu Dissertation.

The Hammer Affidavit was also submitted to show that the Fu Dissertation represented, at least in pertinent part, the inventors' own work; and that the Fu Dissertation was therefore removed as a reference under § 102(a). The Office nevertheless repeated the rejection of independent Claim 1 as being anticipated by the Fu Dissertation under § 102(a).

For reasons that are essentially similar to those given above for the Aucoin presentation (which will not be repeated), it is respectfully submitted that the Hammer Affidavit also removes the Fu Dissertation as a reference.

The Office's attention is again respectfully directed to the admonition in M.P.E.P. § 716.10 that an uncontradicted, unequivocal statement from the applicant regarding the subject matter disclosed in a publication should be accepted as establishing inventorship, unless there is evidence to the contrary.

The Hammer Affidavit provides a clear, uncontradicted, unequivocal statement regarding the subject matter disclosed in the pertinent portions of the Fu Dissertation. See particularly sections 2 and 6 of the Affidavit. Unless the Office produces some countervailing evidence, the uncontradicted statements of the Affidavit must be accepted as true. Accepting those statements as true has the direct, logical consequence of removing the Fu Dissertation as a reference.

The Office is respectfully requested to withdrawn this ground of rejection. Strictly in the alternative, the Office is respectfully requested to clarify with specificity why the Hammer Affidavit is thought not to overcome the rejection, so that a more responsive reply might be made. Further in the alternative, the Office is respectfully requested to suggest any specific modifications to the language of the Affidavit that might help overcome any deficiencies that the Office may identify in the earlier Affidavit.

The § 102(a) Rejection of Claim 53

The sole ground of rejection entered against Claim 53 was that it was said to be anticipated by the *Organic Letters* paper under § 102(a).

The Hammer Affidavit was also submitted to show that the *Organic Letters* paper represented, at least in pertinent part, the inventors' own work; and that the *Organic Letters*

paper was therefore removed as a reference under § 102(a). The Office nevertheless repeated the rejection of independent Claim 53 as being anticipated by the *Organic Letters* paper under § 102(a).

For reasons that are essentially similar to those given above for the Aucoin presentation (which will not be repeated), it is respectfully submitted that the Hammer Affidavit also removes the *Organic Letters* paper as a reference against Claim 53.

The Office's attention is again respectfully directed to the admonition in M.P.E.P. § 716.10 that an uncontradicted, unequivocal statement from the applicant regarding the subject matter disclosed in a publication should be accepted as establishing inventorship, unless there is evidence to the contrary.

The Hammer Affidavit provides a clear, uncontradicted, unequivocal statement regarding the subject matter disclosed in the pertinent portions of the *Organic Letters* paper. See particularly sections 2 and 5 of the Affidavit. Unless the Office produces some countervailing evidence, the uncontradicted statements of the Affidavit must be accepted as true. Accepting those statements as true has the direct, logical consequence of removing the *Organic Letters* paper as a reference.

The Office is respectfully requested to withdrawn this ground of rejection. Strictly in the alternative, the Office is respectfully requested to clarify with specificity why the Hammer Affidavit is thought not to overcome the rejection, so that a more responsive reply might be made. Further in the alternative, the Office is respectfully requested to suggest any specific modifications to the language of the Affidavit that might help overcome any deficiencies that the Office may identify in the earlier Affidavit.

As the January 30, 2006 Office Action at page 7 implicitly acknowledged, the *Organic Letters* paper may be removed as a reference against Claim 53 by showing that the paper is, at least in pertinent part, a publication of the inventors' own work. However, the August 7, 2006 Office Action at page 7 took the position that the showing in the Affidavit did not suffice to remove the paper as a reference.

Applicants' earlier, June 27, 2006 Request for Continued Examination at page 6 had cited M.P.E.P. § 715.03, subpart I(B), second paragraph for the proposition that where the only pertinent disclosure in the reference or activity is a single species of the claimed

genus, an Applicant can overcome the rejection with a 37 C.F.R. § 1.131 Affidavit showing prior possession of the species disclosed in the reference or activity.

The August 7, 2006 Office Action at page 7 observed, however, that the Hammer Affidavit did not satisfy all formalities required of a § 1.131 Affidavit. The undersigned apologizes that, when he drafted the June 27, 2006 Request for Continued Examination, he had overlooked certain distinctions that the Office's Rules make between § 1.131 Affidavits and § 1.132 Affidavits.

However, these distinctions do not alter the ultimate conclusion that the Hammer Affidavit is nevertheless effective to overcome the cited reference, albeit under 37 C.F.R. § 1.132 rather than § 1.131. A § 1.131 Affidavit is not the exclusive means for overcoming a cited reference. A § 1.132 Affidavit is an alternative that is available in many circumstances, including the present one.

M.P.E.P. § 715.01(c), part (I) states in part:

Where the applicant is one of the co-authors of a publication cited against his or her application, he or she may overcome the rejection by filing an affidavit or declaration under 37 C.F.R. 1.131. Alternatively, the applicant may overcome the rejection by filing a specific affidavit or declaration under 37 C.F.R. 1.132 establishing that the article is describing applicant's own work.

M.P.E.P. § 715.01(c) provides at least two alternative routes to overcome a cited reference that constitutes a publication of the inventors' own work: **(a)** one may file a § 1.131 affidavit or declaration; or **(b)** one may file a § 1.132 affidavit or declaration. A § 1.132 affidavit under need not satisfy the special formalities of § 1.131. Under § 715.01(c), it suffices that the Affidavit "establish[es] that the article is describing the applicant's own work." The Hammer Affidavit does exactly that. See particularly Sections 2 and 5 of the Affidavit.

See also M.P.E.P. § 716.10, extensive portions of which were quoted above in the discussion of the Aucoin Oral Presentation. M.P.E.P. § 716.10 expressly states that a

§ 1.132 affidavit may be used to show that a cited publication constitutes the Applicants' own work.

Additionally, Applicants note that the January 30, 2006 and August 7, 2006 Office Actions implicitly acknowledged that the Hammer Affidavit was effective to remove the *Organic Letters* paper as a reference against dependent Claim 54. Once the paper has been removed as a reference against dependent Claim 54, there is no logical reason to continue to cite it against independent Claim 53, when the only pertinent disclosure cited from the *Organic Letters* paper was a single species that has been shown by the § 1.132 affidavit to represent the Applicants' own work.

The Office is respectfully requested to withdrawn this ground of rejection. Strictly in the alternative, the Office is respectfully requested to clarify with specificity why the Hammer Affidavit is thought not to overcome the rejection, so that a more responsive reply might be made. Further in the alternative, the Office is respectfully requested to suggest any specific modifications to the language of the Affidavit that might help overcome any deficiencies that the Office may identify in the earlier Affidavit.

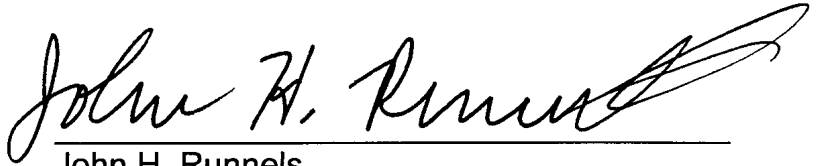
§ 102 Summary

It is respectfully submitted that all prior art rejections have been overcome, or should otherwise be withdrawn.

Conclusion

Allowance of Claims 1, 4, 7-18, 20, 21, and 51-55 at an early date is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, reading "John H. Runnels", written over a horizontal line.

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January 16, 2007